Strengthening Oversight of Food Imports

The Food and Drug Administration (FDA) is proposing two rules that represent a fundamental shift in its oversight of imported foods. The shift is designed to help prevent safety problems before those foods arrive in the United States, rather than having to rely primarily on inspections at U.S. ports of entry.

The proposed Foreign Supplier Verification and Accredited Third Party Certification rules are the next major steps in implementing the FDA Food Safety Modernization Act signed by President Obama in 2011. The law calls for science-based changes to the food safety system to prevent food-borne illnesses.

The new rules would make importers more accountable for food safety, and would establish standards for third-party audits of foreign food producers. These proposals would strengthen FDA's ability to monitor those facilities and respond if there are unsafe practices. A lot of the food we eat is imported—15 percent of the U.S. food supply, including nearly 50 percent of fresh fruit and 20 percent of fresh vegetables.

"We must work toward global solutions to food safety so that whether you serve your family food grown

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locally or imported you can be confident that it is safe," says FDA Commissioner Margaret A. Hamburg, M.D.

The new rules would complement two others proposed in January 2013. The proposed Preventive Controls for Human Food rule would set safety requirements for facilities that process, package or store food for people. And the proposed Produce Safety rule would establish science-based standards for the safe growing, harvesting, packing, and holding of produce on farms.

Foreign Supplier Verification

Brian Pendleton, J.D., a senior policy advisor at FDA, explains that the import rules build on the two FSMA rules proposed earlier. "It's a way to ensure that imports meet U.S. safety standards," he says. "It's all part of a multi-pronged effort to improve the safety of both domestic and imported foods."

The proposed rule would require importers to perform certain activities, generally based on hazards identified as reasonably likely to occur with a food. Importers would have to establish that the foods being exported to the United States have been produced in a manner consistent with U.S. standards. In general, it would require that importers:

- identify hazards associated with each food;
- conduct or obtain documentation of verification activities, which could include onsite auditing, sampling and testing, to provide adequate assurances that the identified hazards are being controlled; and
- take appropriate corrective action if hazards are not being adequately controlled.

"We will continue to check food at our borders. However, rather than relying almost entirely on FDA's investigators at the ports to detect and respond to food safety problems, importers would—for the first time—be held accountable for verifying, in a manner transparent to FDA, that the food they import is safe," says Michael R. Taylor, J.D., deputy commissioner for foods and veterinary medicine.

Accredited Third Party Audits and Certification

This proposed rule would establish a system for the recognition of foreign government agencies or private companies that would accredit third-party auditors of foreign food facilities. These auditors would conduct food safety audits and issue certifications that FDA may use in deciding whether to admit certain imported food into the U.S. that the agency has determined poses a food safety risk.

Both accreditation bodies and auditors would have to meet standards established by FDA to help ensure the quality and credibility of audits in this program.

Charlotte Christin, J.D., a senior policy advisor at FDA, explains that an audit is a comprehensive assessment of a food-producing operation. Under the proposed system, the reports of audits used for certification purposes would be submitted to FDA.

FDA would be closely monitoring these systems and could revoke an accreditation body's recognition or withdraw an auditor's accreditation for good cause, says Christin. "Accountability is key to the success of the program," she says.

Next Steps

The proposed rules have been published in the Federal Register, with a 120-day public-comment period. We invite public input on these proposals. The rules are filed in FDA's official docket at *www.regulations.gov* and can also be accessed at *www.fda.gov/fsma*.

Still to come is the Preventive Controls for Animal Food rule, which would implement preventive controls at animal food facilities that are similar to those proposed for human food.

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